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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-96

September 6, 2000

Lawrence A. Salvo, President
International Diagnostic & Medical Supply Corporation
650 West Avenue, Suite 2508
Miami Beach, Florida 33139

Dear Mr. Salvo:

During an inspection of your firm located at the referenced address on March 14-16 and 23, 2000, FDA Investigator Bonita S. Chester determined that you purchase and distribute the Hema-Strip HIV-1/2 test kit manufactured by Saliva Diagnostic Systems (SDS). The test kit is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection determined that the Hema-Strip HIV-1/2 test kit is in domestic commerce because the test kits are sold by your firm to distributors in the United States. Therefore, the Hema-Strip test HIV-1/2 kit is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) and there is no approved application for investigational device exemption under section 520(g).

The exportation of Hema-Strip HIV-1/2 test kits to Zambia is also in violation of the FD&C Act. The requirements of section 801(e)(2)(C) are not met since you did not receive permission from the Food and Drug Administration to export the devices. In addition, the requirements of section 802(b)(1)(A) are not met since you have not obtained valid marketing authorizations in this country or any listed country.

Additionally, you are in violative of section 802(g) of the Act since you failed to provide simple notification to the Secretary identifying the devices and the country to which such devices were being exported when the exporter first began to export the devices to a country not listed in section 802(b)(l)(A)(i) or (ii) of the Act. For example, Hema-Strip HIV-1/2 test kits were exported to Zambia on July 15, 1999.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, no pending applications for premarket approval (PMAs) will be approved, no premarket notifications [510(k)s] will be found to be substantially equivalent, and no requests for Certificates of Exportability will be issued for products previously distributed.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. The actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violation, including: (1) each step that has or will be taken to correct the current violations; (2) the timeframe within which the corrections will be completed; and (3) any corrections that cannot be completed with 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please respond to Timothy J. Couzins, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4728.

Sincerely,

Edward R. Atkins for

Emma R. Singleton
Director, Florida District

cc: Saliva Diagnostic Systems, Inc.
11719 N.E. 95th Street
Vancouver, Washington 98682